



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 1999

Ms. Eleanor Jones, BSc
Quality Assurance Manager
Sutures, Ltd.
Vauxhall Industrial Estate
Ruabon, Wrexham
LL14 6HA, Wales
United Kingdom

Re: K990432
Trade Name: Surgisorb Surgical Suture
Regulatory Class: II
Product Code: GAM
Dated: April 12, 1999
Received: April 12, 1999

Dear Ms. Jones:

This letter supercedes our May 27, 1999 letter. We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices that were regulated as transitional devices and that have been reclassified into class II. Notice of this reclassification was published in the Federal Register on Wednesday, September 18, 1991 (Vol. 56, No. 18, Pages 47150 and 47151). A copy of this Federal Register can be obtained by calling the Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597. You may, therefore, market the device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The Surgisorb Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.
2. This device may not be manufactured from any material other than homopolymers and copolymers made from glycolide and/or L-lactide. Any deviation of the polymer composition or processing as described in this 510(k) notification must be submitted to FDA in a new premarket notification at least 90 days prior to implementation of the proposed change(s). In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacturing of the Surgisorb Surgical Suture. Any deviation of the source material or processing as described in this 510(k) notification requires submission of a new premarket notification and Food and Drug Administration (FDA) clearance prior to commercial distribution of the modified device.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

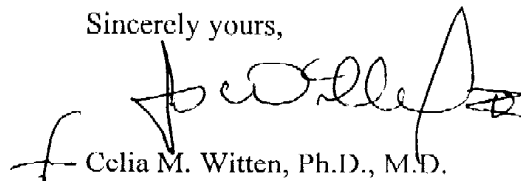
The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', is written over the typed name.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TO DEVICE FOR USE



Vauxhall Industrial Estate, Ruabon, Wrexham, LL14 6HA, Wales, United Kingdom
Telephone: +44 (0)1978 823664 Fax: +44 (0)1978 810669
E-mail: suture@msn.com Internet Address: www.sutures.co.uk

Page 1 of 1

510(k) Number (if known): K990432

Device Name: SURGISORB

Indications For Use:

Surgisorb is indicated for use in general tissue approximation and or ligation, including use in ophthalmic procedures but not for use in cardiac or neurological procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K990432

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1.2-96)



Committed to service and quality.

Reg. No. 1016215 England